OSOM® RSV Test

For *In Vitro* Diagnostic Use
For Prescription Use Only
For Use with Kit Provided Swabs

INSTRUCTIONS FOR USE

IVD $\mathbb{R}_{ONLY}$ REF 1091

CLIA Complexity-WAIVED for use with anterior nasal swab
Certificate of Waiver is required to perform the test in a waived setting
Laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test

INTENDED USE

The OSOM® RSV Test is a rapid immunochromatographic assay for the qualitative detection of respiratory syncytial virus (RSV) nucleoprotein antigen in anterior nasal swab specimens from patients with signs and symptoms of respiratory infections. This test is intended for *in vitro* diagnostic use to aid in the diagnosis of RSV infections in infants and pediatric patients aged 6 months to 6 years old, and adults over 60 years of age.

Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or other management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by viral cell culture or an alternative method, such as an FDA-cleared molecular assay.

SUMMARY AND EXPLANATION OF THE TEST

Respiratory syncytial virus is a prevalent respiratory virus that can cause a range of illnesses, varying from mild to severe, across all age groups. However, it poses a greater risk and severity in infants, young children, older adults, and individuals with weakened immune systems. RSV is the primary cause of acute lower respiratory tract infections in infants, with an estimated 33 million cases reported worldwide.[1-3] Early diagnosis of RSV infection is of utmost importance, and several methods are available to detect it in respiratory samples. Swift and accurate detection of RSV is especially critical for implementing effective infection control measures and preventing hospitalizations, as RSV poses a significant risk, particularly in pediatric wards.[4-5]

The OSOM RSV Test provides a simple, rapid method for the diagnosis of RSV using anterior nasal swab (ANS) specimens. Its user-friendly format and rapid results allow for quick diagnosis and aid in treatment and hospitalization decisions.

PRINCIPLE

The OSOM RSV Test is designed to detect the extracted nucleoprotein antigen-specific to RSV in anterior nasal swab specimens directly collected from patients exhibiting signs or symptoms of a respiratory infection.

When specimens are extracted and added to the sample well of the test device, RSV viral antigens present in the specimen bind to antibodies against RSV nucleoprotein conjugated to gold colloidal particles. The antigen-conjugate immunocomplexes migrate across the test strip and are captured at the test line of the nitrocellulose membrane. Test results are interpreted at 15-20 minutes visually.

An RSV positive result is indicated by the presence of two pinkish-red colored lines, one in the control line "C" and the other in the test line "T." Conversely, an RSV

negative result is indicated by the presence of only one colored line in the control line "C." The presence of the control line "C" in the test window is crucial for self-validation. It should always appear at the designated position "C" in a valid test result. Any result without this control line is invalid.

REAGENTS AND MATERIALS

Provided

27* - Test devices in sealed aluminum foil pouch with desiccant
27* - Reagent tubes prefilled with extraction buffer (350 µL) and dropper tips
25 - Sample collection swabs (Anterior Nasal)
1 - Positive control swab (noninfectious RSV antigen)
1 - Negative control swab (noninfectious nasal clinical matrix)
1 - Instructions for Use (IFU)
1 - Quick Reference Guide (QRG)

***NOTE:** Two extra test devices have been included for external QC testing.

Required but not provided

- Timer
- Tube rack for specimens
- Any necessary personal protective equipment

STORAGE AND STABILITY

- The test kit should be stored at 2-30°C in the original sealed pouch. Do not freeze.
- Bring all test components to room temperature at least 30 minutes prior to use.
- The freshly collected anterior nasal swab specimen is recommended to be processed no later than one hour after specimen collection when kept at room temperature (15-30°C), or within 24 hours when stored at 2-8°C. Do not freeze swab specimens before testing.
- The test is stable until the expiration date printed on the outside of the box. Do not use after the expiration date.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- For prescription use only.
- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- For use with kit provided swabs. Use only swabs provided with the kit.
- Do not use if any of the test kit contents or packaging is damaged.
- Do not use any test component after the expiration date which is printed on the outer packaging.
- Do not interchange kit contents from different lots.
- Test components are single-use. Do not re-use.
- Do not touch the swab tip.
- Once opened, the test card should be used within 90 minutes.
- Do not read test results before 15 minutes or after 20 minutes. Results read before 15 minutes or after 20 minutes may lead to a false positive, false negative, or invalid result.
- Ensure that testing and result interpretation are conducted in a well-lit space with sufficient lighting.
- Do not eat, drink, or smoke in the area where the specimens and kit contents are handled.
- Do not use the kit to evaluate patient specimens if either the positive control swab or negative control swab fails to give the expected results.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit components.

- Nitrile or latex gloves should be worn when performing this test.
- Dispose of used contents as biohazardous waste in accordance with federal, state, and local requirements.
- Handle all specimens as though they contain infectious agents.
- Observe established precautions against microbiological hazards throughout the procedure.
- The Extraction Reagent contains potentially harmful chemicals (see table below). If the test solution contacts the skin or eye, flush with copious amounts of water.

If irritation persists, seek medical advice:
visit https://www.poison.org/contact-us Or call 1-800-222-1222.

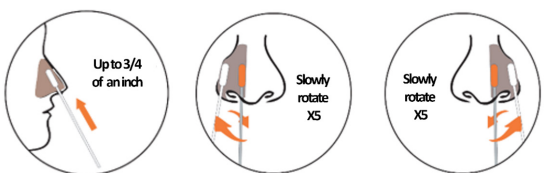
Chemical	Harms (GHS Code) for each ingredient	Concentration
Sodium Azide	Acute Tox. 2 (Oral) (H300) Acute Tox. 1 (Dermal) (H310)	0.09%
Gentamicin	Skin sensitization (H317)	0.004%
CHAPS Hydrate	Skin irritation (H315) Eye irritation (H319) Reproductive toxicity (H360) Specific target organ toxicity Respiratory system (H335)	1.0%
Triton X-100	Skin sensitization (H317)	1.0%
Amphotericin B	Specific target organ toxicity Respiratory system (H335)	0.1%

SPECIMEN COLLECTION

The acceptable specimen type for testing with the OSOM RSV Test is a direct anterior nasal swab specimen. It is essential that correct specimen collection must be followed. Inadequate specimen collection, improper specimen handling and/or transport may yield false results; therefore, specimen collection requires specific training and guidance due to the importance of specimen quality to obtain accurate test results.

Freshly collected specimens should be processed as soon as possible, but no later than one hour (when kept at room temperature) or up to 24 hours (when stored at 2-8°C) after specimen collection. Specimens in extraction buffer can be processed up to 30 minutes after collection when kept at room temperature.

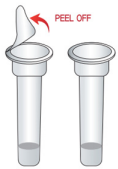
To collect the anterior nasal swab sample, tilt the patient's head back 70 degrees and insert the soft end of the swab into patient's nostril no more than ¾ of an inch into the nose (no more than ½ inch if swabbing a child). Slowly rotate the swab, gently pressing against the inside of patient's nostril at least 5 times for a total of 15 seconds. Get as much nasal discharge as possible on the soft end of the swab. Gently remove the swab. Use the same end of the swab and repeat the same steps on the other nostril. Refer to Specimen Collection: Nose and Throat at
https://elsevier.health/en-US/preview/specimen-collection-nose-and-throat



TEST PROCEDURE AND PROTOCOL

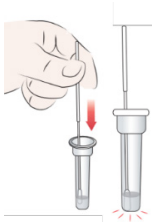
Collect specimens according to instructions in “Specimen Collection”. Test device and sample should be brought to room temperature (15-30°C) prior to testing. Conduct all testing on a level surface and ambient conditions.

1



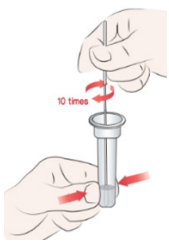
Peel off the aluminum foil from the top of the Reagent Tube containing 350 µL of extraction buffer.

2



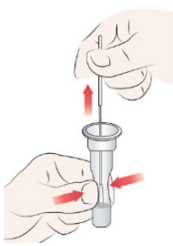
Insert the collected swab specimen into the Reagent Tube until the swab head touches the bottom of the tube.

3



Hold the swab head at the bottom of the tube tightly by squeezing the tube. Then stir the swab at least **10 times**.

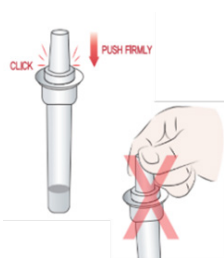
4



Remove the swab while squeezing the sides of the tube to release the maximum amount of liquid from the swab head. Properly discard the swab.

NOTE: Do Not freeze swab specimens before testing.

5

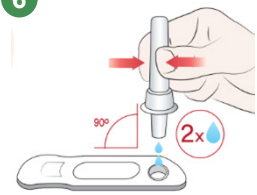


Firmly push on the provided Dropper tip to close the Reagent tube.

NOTE: Do NOT touch or grab the hole of the dropper tip.

Specimens in extraction buffer can be processed up to 30 minutes after collection when kept at room temperature.

6



Invert the processed Reagent Tube and hold it vertically above the sample well. Squeeze the tube gently and dispense **two (2) drops** of the sample into the sample well of the test device.

NOTE: Too few drops can result in invalid results, and too many drops could produce incorrect results.

7

Read the results at 15 minutes visually. Do not read result more than 20 minutes after the sample application.

NOTE: False negative or false positive results can occur if read before or after 15-20 minutes.

RESULTS INTERPRETATION

Positive

If the Control (C) line and the Test (T) line are visible, the test is positive. Any visible faint red or pink Test (T) line with a visible Control (C) line should be read as positive.

Negative

If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative. A negative test result indicates that the virus that causes RSV was not detected in the sample.

NOTE: Negative results are presumptive and may be confirmed with a molecular assay, if necessary, for patient management.

Invalid

If a Control (C) line is not visible, the test is not valid.

Re-test with a new swab and a new test cassette. If the problem persists, please call +1-800-332-1042.

QUALITY CONTROL

Internal Quality Control: The presence of a pinkish-red colored band in the Control area of the window acts as an internal control to ensure adequate migration has occurred but does not determine if an adequate sample has been added. In the absence of this Control line, the test is invalid and must be repeated. If the control line does not develop in 15 minutes, the test result is considered invalid, and retesting with a new device is recommended.

If the internal procedural control line is still absent on the retest, please contact SEKISUI Diagnostics Technical Services at +1-800-332-1042 or techservices@sekisuidiagnostics.com.

External Control: Positive and negative control swabs are supplied with each kit. These controls provide additional quality control material to assess that the test kit reagents perform as expected. Process the controls in the same manner as the clinical sample swab, and conduct the assay as described in the Test Procedure section. Controls should minimally be run before using each new lot or shipment of OSOM RSV Test kit, at regular intervals afterward, or any time when the validity of the test results is questioned. All users should follow local, state, and federal regulations regarding quality control procedures.

If the controls do not perform as expected, do not report patient results. Please contact SEKISUI Diagnostics Technical Services at +1-800-332-1042 or techservices@sekisuidiagnostics.com.

LIMITATIONS

- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with RSV as compared to a molecular test, especially in samples with low viral load.
- Viral transport media (VTM) should not be used with this test.
- Negative test results are not intended to rule out other non-RSV viral or bacterial infections.
- Positive test results do not rule out co-infections with other bacterial or viral pathogens.
- All negative test results obtained with the OSOM RSV Test are presumptive and confirmation with a molecular assay may be necessary.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- Results from testing with the OSOM RSV Test should not be used as the sole basis to diagnose or exclude RSV infection or to determine infection status.
- This test detects both viable (live) and non-viable RSV. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample. A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly.
- Results from the device should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
- The OSOM RSV Test is a qualitative test and does not provide information on the viral concentration present in the specimen.
- Positive and negative predictive values are highly dependent on prevalence rates. Positive test results are more likely to represent false positive results during periods of little/no RSV activity when disease prevalence is low. False-negative test results are more likely during peak RSV activity when the prevalence of disease is high.
- The OSOM RSV Test has been evaluated for use with human specimen material only.
- Monoclonal antibodies may fail to detect, or detect with less sensitivity, RSV viruses that have undergone minor amino acid changes in the target epitope region.
- The performance of this test has not been evaluated for use in patients without signs

and symptoms of respiratory infection.
- The validity of the OSOM RSV Test has not been proven for identification/ confirmation of tissue culture isolates and should not be used in this capacity.
- Therapeutic anti-RSV monoclonal antibodies may interfere with the OSOM RSV Test.
- Performance characteristics have not been established for use with patients aged 7 to 59 years or for immunocompromised patients.
- There is a risk of erroneous results (i.e., false negatives) due to the presence of novel, emerging respiratory viral variants (e.g., specific strains or isolates). The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between November 2023 and March 2024. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of RSV and their prevalence, which change over time.

EXPECTED VALUE

The rate of positivity as determined by the OSOM RSV Test during the 2023-2024 clinical study was 11.7% (96/818).

CLINICAL PERFORMANCE

The clinical performance of the OSOM RSV Test was established with 818 anterior nasal samples prospectively collected from subjects between November 2023 and March 2024 at six clinical CLIA waived sites in the U.S. Samples were collected from sequentially enrolled subjects who presented with symptoms of respiratory infection. Two anterior nasal swabs were collected from each study subject during the same visit. Specimens were collected from pediatric patients between 6 months to 6 years of age and adult patients 60 years or older. Of those, 29% (237/818) were from subjects 6 months to 2 years old, 36.9% (302/818) were from patients 2 to 6 years of age, and 34.1% (279/818) were from patients 60 years or older. Samples were tested with the OSOM RSV Test. All subjects were confirmed as positive or negative by the FDA cleared RT-PCR method, used as the comparator method for the study. OSOM RSV Test was performed by operators who had no prior experience in the laboratory and were representative of the intended users in CLIA waived settings. Operators used only the QRG to conduct testing without training provided. All testing was conducted by operators in a blinded fashion.

Out of the 111 samples that tested positive with the comparator RT-PCR test, 93 were also positive and 18 were negative using OSOM RSV Test. Additionally, 704 out of 707 samples that were negative on RT-PCR were also negative on the OSOM RSV Test. The calculated percent agreements between the OSOM RSV Test and RT-PCR results are presented below.

OSOM RSV Test	Comparator RT-PCR		Total
	Positive	Negative	
Positive	93	3	96
Negative	18	704	722
Total	111	707	818
Positive Percent Agreement (PPA) = (93/111) x 100% = 83.8% (95% CI: 75.8%-89.5%)			
Negative Percent Agreement (NPA) = (704/707) x 100% = 99.6% (95% CI: 98.8%-99.9%)			

ASSAY LIMIT OF DETECTION

To verify the analytical sensitivity of the OSOM RSV Test, the Limit of Detection (LoD) was established using serial dilutions of two RSV A strains and two RSV B strains. Contrived samples were prepared by spiking the strains into pooled negative nasal fluid confirmed negative for RSV. A preliminary LoD was determined by spiking 50 µL

of serially diluted sample onto the sample collection swab heads in three replicates and tested using the OSOM RSV Test. The confirmatory LoD test was performed at the selected preliminary LoD concentration with a total of 30 replicates. Based on the results from this study, the LoDs for each strain tested are presented below.

RSV subtype	Strain	LoD	% Positive
A	Long	1.6×10^3 $TCID_{50}$/mL	100.0%
	A-2	2.0×10^4 $TCID_{50}$/mL	96.7%
B	18537	4.0×10^3 $TCID_{50}$/mL	100.0%
	B1	3.5×10^3 $TCID_{50}$/mL	100.0%

ANALYTICAL REACTIVITY (INCLUSIVITY)

The analytical reactivity study was conducted with the currently available 9 clinical isolated strains of RSV. Ten-fold dilutions of virus stocks were prepared in pooled negative nasal fluid matrix and 50 µL of each dilution were pipetted onto the swabs. Each strain was tested in 5 replicates. The lowest concentration of each strain that resulted in 100% detection (5/5) is presented below.

RSV subtype	Strain	Concentration Detected (5/5)
A	1998/3-2	1.6×10^4 $TCID_{50}$/mL
	1998/12-21	2.8×10^1 $TCID_{50}$/mL
	2000/3-4	3.2×10^0 $TCID_{50}$/mL
	2001/3-12	1.4×10^3 $TCID_{50}$/mL
	ARG/177/2006	8.9×10^2 $TCID_{50}$/mL
	2001/2-20	8.9×10^3 $TCID_{50}$/mL
	1997/12-35	1.3×10^3 $TCID_{50}$/mL
B	9320	3.5×10^3 $TCID_{50}$/mL
	WV/14617/85	1.1×10^3 $TCID_{50}$/mL

HIGH-DOSE HOOK EFFECT

The OSOM RSV Test showed no high-dose hook effect when subjected to RSV Long at a concentration of 1.6×10^7 $TCID_{50}$/mL, A2 at 1.6×10^8 $TCID_{50}$/mL, 18537 at 1.6×10^7 $TCID_{50}$/mL, and B1 at 2.8×10^6 $TCID_{50}$/mL.

ASSAY CROSS-REACTIVITY AND MICROBIAL INTERFERENCE

Cross-reactivity of the OSOM RSV Test was evaluated by testing 51 potential pathogens, including bacteria (21), fungus (1), and viruses (29) that could potentially cross-react with the OSOM RSV Test. The final concentration of each organism is described in the table below. The microbial interference was also performed with the same panel of microorganisms at the same concentrations in the samples that were spiked with RSV at 3x LoD. The samples were tested in triplicates for both cross-reactivity and interference studies. No cross-reactivity and no microbial interference were observed. The results for cross-reactivity and microbial interference are presented in the table below.

Pathogen	Concentration Tested	Cross-Reactivity/ Microbial/ Interference
Bordetella pertussis	1×10^6 cfu/mL	No
Candida albicans, ZMC	1×10^6 cfu/mL	No
Chlamydophila pneumoniae, AR-39	1×10^6 IFU/mL	No

Pathogen	Concentration Tested	Cross-Reactivity/ Microbial/ Interference
Corynebacterium diphtheriae	1×10^6 cfu/mL	No
Escherichia coli	1×10^6 cfu/mL	No
Haemophilus influenzae, B	1×10^6 cfu/mL	No
Lactobacillus acidophilus	1×10^6 cfu/mL	No
Legionella pneumophila	1×10^6 cfu/mL	No
Moraxella catarrhalis	1×10^6 cfu/mL	No
Mycobacterium tuberculosis, H37Ra-1	1×10^6 cfu/mL	No
Mycoplasma pneumoniae	1×10^6 cfu/mL	No
Neisseria meningitidis, A	1×10^6 cfu/mL	No
Neisseria mucosa, AmMs 138	1×10^6 cfu/mL	No
Neisseria subflava	1×10^6 cfu/mL	No
Pneumocystis jirovecii, W303-Pji	1×10^6 cfu/mL	No
Pseudomonas aeruginosa, Boston 41501	1×10^6 cfu/mL	No
Staphylococcus aureus, MRSA;COL	1×10^6 cfu/mL	No
Staphylococcus epidermidis, MRSE; RP62A	1×10^6 cfu/mL	No
Streptococcus mutans	1×10^6 cfu/mL	No
Streptococcus pneumoniae, 19F	1×10^6 cfu/mL	No
Streptococcus pyogenes, Bruno	1×10^6 cfu/mL	No
Streptococcus salivarius	1×10^6 cfu/mL	No
Adenovirus, 2	8.5×10^5 $TCID_{50}$/mL	No
Coronavirus, OC43	3.8×10^5 $TCID_{50}$/mL	No
Coxsackievirus, B4	1.0×10^5 $TCID_{50}$/mL	No
Enterovirus 71, MP4	1.6×10^5 $TCID_{50}$/mL	No
Epstein-Barr Virus, B95-8	2.94×10^5 cp/mL	No
Human Coronavirus, 229E	1.6×10^5 $TCID_{50}$/mL	No
Human Coronavirus, NL63	8.0×10^3 $TCID_{50}$/mL	No
Human Herpesvirus 5, Merlin	8.0×10^4 $TCID_{50}$/mL	No
Human Metapneumovirus, TN/83-1211	2.8×10^5 $TCID_{50}$/mL	No
Human Parainfluenza Virus 1/FRA/ 29221106/2009	8.9×10^5 $TCID_{50}$/mL	No
Human Parainfluenza Virus 2, Greer	1.0×10^5 $TCID_{50}$/mL	No
Human Parainfluenza Virus 3, NIH 47885	1.6×10^5 $TCID_{50}$/mL	No
Human Parainfluenza Virus 4B, 19503	5.0×10^5 $TCID_{50}$/mL	No
Influenza A (H1N1), A/PR/8/34	1.6×10^5 $CEID_{50}$/mL	No
Influenza A (H3N2)/Singapore/ INFIMH-16-0019/16	1.0×10^5 $TCID_{50}$/mL	No
Influenza A (H3N2), A/California/ 2/2014	1.0×10^5 $TCID_{50}$/mL	No
Influenza A (H3N2), A/Hong Kong/ 4801/2014	9.6×10^5 $CEID_{50}$/mL	No

Pathogen	Concentration Tested	Cross-Reactivity/ Microbial/ Interference
Influenza A (H3N2), A/Switzerland/ 9715293/2013	1.6×10^5 $CEID_{50}$/mL	No
Influenza B/Christchurch/33/2004 (Yamagata Lineage)	1.6×10^5 $TCID_{50}$/mL	No
Influenza B/Florida/4/2006	2.8×10^5 $CEID_{50}$/mL	No
Influenza B/Hong Kong/330/2001	1.8×10^5 $CEID_{50}$/mL	No
Influenza B/Malaysia/2506/04	2.8×10^5 $CEID_{50}$/mL	No
Influenza B/Sydney/507/2006 (Yamagata Lineage)	1.6×10^5 $TCID_{50}$/mL	No
Measles Virus, Edmonston	1.7×10^4 $TCID_{50}$/mL	No
MERS-CoV, EMC/2012	1.0×10^5 $TCID_{50}$/mL	No
Mumps Virus, MuV/Iowa.US/2006	1.0×10^5 $TCID_{50}$/mL	No
Rhinovirus 20, 15-CV19	1.0×10^5 $TCID_{50}$/mL	No
SARS-CoV, Urbani strain	1.0×10^5 pfu/mL	No
SARS-CoV-2 (Omicron) hCoV-19/ USA/ MD-HP20874/2021	1.95×10^4 $TCID_{50}$/mL	No

ENDOGENOUS/EXOGENOUS INTERFERENCE

To assess endogenous/exogenous interference with the performance of the OSOM RSV Test, positive and negative samples were tested with potentially interfering substances that may be found in the upper respiratory tract. This study was performed to demonstrate that thirty-four (34) potentially interfering substances do not interfere with the detection of RSV in OSOM RSV Test.

Interfering Substances	Concentration	Interference (Yes/No)
Nasal Spray 1	15% v/v	No
Nasal Spray 2	15% v/v	No
Nasal Spray 3	15% v/v	No
Nasal Spray 4	15% v/v	No
Budesonide Nasal Spray	15% v/v	No
NASONEX 24 hr Allergy	15% v/v	No
Nasacort Allergy 24HR	15% v/v	No
Sore Throat (Oral Pain Reliever spay)	15% v/v	No
ZICAM® Oral mist	15% v/v	No
Sore Throat Lozenges	15% w/v	No
Zinc Cold Therapy	15% w/v	No
Homeopathic Allergy Nasal Spray	15% v/v	No
NasoGEL (Gel Spray)	15% v/v	No
Nasalcrom® Nasal Allergy spray	15% v/v	No
Histaminum 30C	15% w/v	No
Skin relief hand cream	1% w/v	No

Interfering Substances	Concentration	Interference (Yes/No)
Hand Soap Fresh Breeze Scent	1% w/v	No
Antibacterial liquid Hand Soap	1% w/v	No
Hand Sanitizer Gel	1% w/v	No
Disinfectant Spray	1% v/v	No
Acetylsalicylic acid	3.00×10^{1} µg/mL	No
Beclomethasone Dipropionate	5.04 µg/mL	No
Dexamethasone	1.20×10^{1} µg/mL	No
Flunisolide	870 µg/mL	No
Molnupiravir	3.29 mg/mL	No
Mometasone furoate	4.50×10^{-4} µg/mL	No
Mupirocin	1.50×10^{0} µg/mL	No
Oseltamivir phosphate	3.99×10^{-1} µg/mL	No
Remdesivir	240 µg/mL	No
Tobramycin	3.30×10^{1} µg/mL	No
Zanamivir	30 mg/mL	No
Whole Blood	2.5%	No
Mucin-bovine submaxillary glands (Type I-S)	5 mg/mL	No
Purified Human Neutrophils	5×10^{6} cells/mL	No

REPRODUCIBILITY

The reproducibility of the OSOM RSV Test was evaluated at three external CLIA-waived sites with a total of seven untrained operators and one internal site with three trained operators. The reproducibility panel was composed of a panel of 12 contrived RSV samples ranging from moderate positive samples (3x LoD), low positive samples (1x LoD), high negative samples (0.1x LoD), and negative samples. The results of this study revealed a 100% agreement with expected results, as indicated below.

Sample	No of Positive Result/No of Total Tested (% Positive Rate)				Total	
	External Site 1 (2 operators)	External Site 2 (3 operators)	External Site 3 (2 operators)	Internal Site 4 (3 operators)	Agreement	95% CI
True Negative	0/30 (0%)	0/45 (0%)	0/30 (0%)	0/45 (0%)	150/150 (100%)	97.5-100.0
High Negative	0/30 (0%)	0/45 (0%)	0/30 (0%)	0/45 (0%)	150/150 (100%)	97.5-100.0
Low Positive	30/30 (100%)	45/45 (100%)	30/30 (100%)	45/45 (100%)	150/150 (100%)	97.5-100.0
Medium Positive	30/30 (100%)	45/45 (100%)	30/30 (100%)	45/45 (100%)	150/150 (100%)	97.5-100.0

CLIA WAIVER STUDY

The accuracy of the OSOM RSV Test was evaluated in a prospective clinical study during November 2023 to March 2024 at six intended-use CLIA-waived sites. The sites consisted of urgent care clinic, adult care center, and physicians' offices. A total of nine (9) operators, representative of CLIA-waived site personnel (intended users)

with no prior laboratory experience, participated in the study without any training on the use of the test. The results obtained from the OSOM RSV Test by the intended users were compared with those obtained using an FDA-cleared RT-PCR method. This study evaluated 818 prospectively collected specimens, of which 111 tested positive and 707 tested negative by the FDA-cleared RT-PCR method. The comparison of the OSOM RSV Test results with the comparator method results showed PPA of 83.8% (93/111) with a 95% CI of 75.8%-89.5%, NPA of 99.6% (704/707) with a 95% CI of 98.8%-99.9%. A summary of these results is presented in the Clinical Performance section.

A near-the-cutoff study was conducted to demonstrate the capability of untrained users to accurately test samples with concentrations near the assay cutoff. This study was conducted at three CLIA-waived intended-use sites using simulated swab samples as part of the reproducibility study. The samples were spiked with RSV virus targeting 1x LoD concentration (low positive ≈ 95% positivity) and high negative samples (0.1x LoD). The swabs were provided to the operators in blinded and randomized panels for testing with the OSOM RSV Test according to the test procedure. A total of seven (7) untrained operators participated, with each site having two or three operators. Each operator tested 15 low positive and 15 negative samples over five nonconsecutive days. The results of this study revealed a 100% agreement with expected results. A summary of these results is presented in the Reproducibility section.

Using risk analysis as a guide, analytical flex studies were conducted. The studies demonstrated that the test was not sensitive to the environmental stresses or potential user errors.

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GLOSSARY

	Caution: Federal law restricts this device to sale by or on the order of a physician
	Catalog number
	Batch code
	Use-by date
	Consult instructions for use
	*In Vitro* Diagnostic Medical Device
	Temperature limit
	Positive control
	Negative control
	Do not re-use
	Manufacturer
	Contains sufficient for <n> tests
	Attention, see instructions for use

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